Kentucky Department for Medicaid Services
Drug Review and Options for Consideration

The following table lists the agenda items scheduled for review, as well as options for consideration, at the November 17, 2016 meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Review	Options for Consideration
New Products to Market: **Qbrelis™**	Non-prefer in PDL class: *Angiotensin Modulators* **Length of Authorization:** 12 months Qbrelis (lisinopril) oral solution is indicated for the treatment of hypertension in adults and pediatric patients ≥ 6 years old, as adjunct therapy for systolic heart failure in adults, and for reduction of mortality in acute myocardial infarction (AMI) in adults. **Approval Criteria:** ▪ 6 - 17 years of age; AND ▪ Have diagnosis of hypertension; AND ▪ Have eGFR > 30 mL/min/1.73m^2; AND ▪ Not be able to take an oral capsule or tablet. **OR;** ▪ Patient must not be pregnant; AND ▪ ≥ 18 years of age; AND ▪ Have diagnosis of heart failure, acute myocardial infarction, or hypertension; AND ▪ Not be able to take an oral capsule or tablet. **Quantity Limit** = adults: 40mg/day; pediatrics - 0.61mg/kg/day or 40mg per day, whichever is lower (to be determined during the clinical review of the PA request).

Single Agent Review	Options for Consideration
New Products to Market: **Byvalson™**	Non-prefer in the PDL class: *Angiotensin Modulator Combinations* **Length of Authorization**: 12 months Byvalson (nebivolol/valsartan) is the combination of a beta-blocker and an angiotensin II receptor blocker (ARB) available as a 5 mg/ 80 mg tablet. It is indicated for the treatment of hypertension (HTN). **Approval Criteria:** Patient has had a trial and failure of 2 first-line HTN therapies comprised of multiple single agents used in combination. Example; Calcium Channel Blocker (CCB) + Angiotensin Converting Enzyme Inhibitor (ACEI). **Quantity Limit** = 1 tablet per day
New Products to Market: **Zurampic®**	Non-prefer in PDL class: *Antihyperuricemics* **Length of Authorization:** 12 months Zurampic (lesinurad) 200 mg tablets are indicated for use in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. **Approval Criteria:** ▪ ≥18 years of age; AND ▪ Have symptomatic hyperuricemia associated with gout; AND ▪ Have documented trial and failure of xanthine oxidase inhibitor monotherapy at maximum tolerated dose; AND ▪ Using lesinurad in combination with a xanthine oxidase inhibitor; AND ▪ Patient does not have severe renal impairment (CrCl < 45 mL/min), ESRD, kidney transplant, or is on dialysis; AND ▪ Patient does not have tumor lysis syndrome or Lesch-Nyhan syndrome. **Quantity Limit** = 1 tablet per day
New Products to Market: **Relistor®** (oral)	Non-prefer in PDL class: *GI Motility, Chronic* **Length of Authorization:** 6 months Relistor (methylnaltrexone bromide) tablets are indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. **Approval Criteria:** ▪ ≥18 years of age; AND ▪ Patient does not have known or suspected mechanical gastrointestinal obstruction; AND ▪ If patient is female, must not currently be breastfeeding ; AND

Single Agent Review	Options for Consideration
	▪ Response to standard laxative therapy is inadequate (<3 bowel movements in preceding 7 days). Standard therapy is defined as routine, scheduled use of 3 or more of the following: ▪ Dietary changes ▪ Stool softeners ▪ Stimulant laxatives ▪ Osmotic or saline laxatives ▪ Bulk forming laxatives ▪ Lubricants **Quantity Limit** = 3 tablets per day
New Products to Market: **Epclusa®**	Prefer in PDL class: *Direct-Acting Antivirals* Prefer for Genotypes 2 and 3 ONLY. **Length of Authorization: 12 weeks** Eplcusa (sofosbuvir/velpatasvir) 400 mg/100 mg tablets is a fixed-dose combination of a nucleotide analog NS5B polymerase inhibitor (sofosbuvir) and an NS5A inhibitor (velpatasvir) indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection, with or without compensated cirrhosis, or with decompensated cirrhosis in combination with ribavirin. All class criteria must be met for approval. **Quantity Limit**: 28 tablets per 28 days.
New Products to Market: **Otovel™**	Non-prefer in PDL class: *Otic Antibiotics* **Length of Authorization**: 7 days Otovel™ (ciprofloxacin/fluocinolone acetonide) solution, for otic use, is a combination of an antibacterial and a corticosteroid. Each single-dose vial contains ciprofloxacin 0.3% along with fluocinolone acetonide 0.025%. Otovel solution is indicated for the treatment of acute otitis media with tympanostomy tubes in pediatric patients aged 6 months and older due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis*, and *Pseudomonas aeruginosa*, for a duration of no more than 7 days. **Approval Criteria:** ▪ Patient ≥ 6 months of age; AND ▪ Diagnosis of acute otitis media; AND ▪ Patient has tympanostomy tubes; AND ▪ Patient does not have a viral infection of the external ear canal, nor any fungal otic infection.

Full Class Reviews	Options for Consideration
Antipsychotics	**First Generation:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities, at least 1 representing an agent from each of the potency groups, should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require prior authorization. ▪ Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back. ▪ For any new chemical entity in the First Generation Antipsychotics class, require a PA until reviewed by the P&T Advisory Committee. **Second Generation:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 5 unique chemical entities should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require prior approval. ▪ Continue quantity limits on agents in this class. ▪ Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back. ▪ For any new chemical entity in the Second-Generation Antipsychotics class, require a PA until reviewed by the P&T Advisory Committee. **Injectables:** ▪ DMS to select preferred agent(s) based on economic evaluation. Generic formulations of first generation injectable antipsychotics should be preferred. Additionally, 2 unique second generation injectable antipsychotics, 1 of which should have a duration of action of 2 weeks or longer, should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require prior approval. ▪ Continue quantity limits on agents in this class. ▪ Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back. ▪ For any new chemical entity in the Antipsychotics class, require a PA until reviewed by the P&T Advisory Committee. **Combination Products (Symbyax®):** ▪ DMS to select preferred agent(s) based on economic evaluation. ▪ Agents not selected as preferred will be considered non-preferred and require prior approval. ▪ Continue quantity limits on agents in this class. ▪ Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back. ▪ For any new chemical entity in the Second Generation Antipsychotic and SSRI Combination class, require a PA until

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	reviewed by the P&T Advisory Committee.
Oncology Oral - Other	▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred. ▪ Continue quantity limits based on FDA-approved maximum dose. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ DMS to allow continuation of therapy for existing users of non-preferred, single-source branded products via a 90-day look back. ▪ For any new chemical entity in the *Oral Oncology, Other* class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmics, Allergic Conjunctivitis	**Antihistamines:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Antihistamines* class, require a PA until reviewed by the P&T Advisory Committee. **Mast-Cell Stabilizers:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Mast Cell Stabilizers* class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmics, Antibiotic-Steroid Combinations	▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Antibiotics-Steroid Combinations* class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmics, Anti-inflammatories	**NSAIDs:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic NSAIDs* class, require a PA until reviewed by the P&T Advisory Committee. **Steroids/Combinations:**

Full Class Reviews	Options for Consideration
	▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 3 unique chemical entities should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Anti-inflammatory Steroids* class, require a PA until reviewed by the P&T Advisory Committee.

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Ophthalmics, Anti-inflammatories/ Immunomodulators	New Product to class: Xiidra™ Non-prefer **Length of Authorization**: 6 months initial; 12 months re-approval Xiidra (lifitegrast) 5% ophthalmic solution is a lymphocyte function-associated antigen-1 (LFA-1) antagonist approved for treating the signs and symptoms of dry eye disease in adults. **Initial Approval Criteria:** ▪ ≥17 years of age; AND – Have a diagnosis of chronic dry eye disease (DED) (e.g., not associated with seasonal allergies) or chronic eye dryness secondary to Sjögren's syndrome; AND – Have presence of conjunctival redness; AND – Have one of the following: ▪ Corneal fluorescein staining score of ≥ 2 points in any field on a 0 to 4 point scale; OR ▪ Schirmer tear test (STT) of 1 to 10 mm in 5 minutes; AND – NOT concurrently using ophthalmic cyclosporine (Restasis); AND – Have had an adequate trial and failure of over-the-counter (OTC) artificial tears (use of at least 4 times daily). **Renewal Criteria:** Patient must: ▪ Have improvement in signs of DED as measured by at least 1 of the following: – Decrease in corneal fluorescein staining score; OR – Increase in number of mm per 5 minutes using Schirmer tear test; AND ▪ Decrease in conjunctival redness; AND ▪ Have improvement in ocular discomfort; AND ▪ NOT be using concurrent ophthalmic cyclosporine (Restasis); AND ▪ Not be using supplemental artificial tears concurrently with lifitegrast (Xiidra). **Quantity Limit**: 60 single-use containers per 30 days. ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Immunomodulator* class, require a PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
Ophthalmics, Glaucoma	**Beta-blockers:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Glaucoma, Beta-blockers* class, require a PA until reviewed by the P&T Advisory Committee. **Carbonic Anhydrase Inhibitors:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Glaucoma, Carbonic Anhydrase Inhibitors* class, require a PA until reviewed by the P&T Advisory Committee. **Combinations:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 combination product containing an ophthalmic beta-agonist should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Combinations for Glaucoma* class, require a PA until reviewed by the P&T Advisory Committee. **Direct-Acting Miotics:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Glaucoma Direct-Acting Miotics* class, require a PA until reviewed by the P&T Advisory Committee. **Prostaglandin Agonists:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ Continue current quantity limits on agents in this class. ▪ For any new chemical entity in the *Ophthalmic Glaucoma, Prostaglandin Analogs* class, require a PA until reviewed by the P&T Advisory Committee. **Sympathomimetics:** ▪ DMS to select preferred agent(s) based on economic evaluation;

Full Class Reviews	Options for Consideration
	however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Sympathomimetics* class, require a PA until reviewed by the P&T Advisory Committee.

Consent Agenda	Options for Consideration
	For the following therapeutic classes, there are no recommended changes to the currently posted Preferred Drug List agent statuses.
	▪ Antianginal & Anti-ischemic Agents ▪ Antiarrhythmics, Oral ▪ Antibiotics, Topical ▪ Anticoagulants ▪ Antiemetic & Antivertigo Agents ▪ BPH Agents ▪ Bronchodilators, Beta-Agonists ▪ Calcium Channel Blockers ▪ Cytokine & CAM Antagonists ▪ H. Pylori Agents ▪ Hepatitis C Agents (Interferons & Ribavirins) ▪ Laxatives & Cathartics ▪ Lipotropics, Other ▪ Neuropathic Pain ▪ Oncology Oral – Hematologic ▪ Ophthalmics, Antibiotics ▪ Ophthalmics, Antivirals ▪ Ophthalmics, Mydriatics ▪ Platelet Aggregation Inhibitors ▪ Proton Pump Inhibitors ▪ Stimulants & Related Agents ▪ Thrombopoiesis Stimulating Proteins